

K061541

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant:

Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

AUG 21 2006

Contact:

James A. Lee
Senior Regulatory Affairs Specialist

Device Identification:

Common Name:

Bipolar Working Element/Cutting Loop/Cable

Trade Name: (optional)


The KSEA Bipolar Electrotome

Indication: The KSEA Bipolar Electrotome is intended for use in combination with a resectoscope and a sheath by qualified surgeons to resect, ablate or coagulate tissue via a high frequency electrical current waveform during various endoscopic urological procedures. These procedures include bladder tumor diagnosis and resection, transurethral prostatic and bladder biopsy, transurethral prostatic resection, removal of urethral calculus, and treatment of vesical neck constriction.

Device Description: The KSEA Bipolar Electrotome is a manual surgical device, featuring a working element, a single-use cutting loop, and a high frequency cable. It is designed to be used with a 4 mm resectoscope and a 24 or 26 Fr resectoscope sheath.

Substantial Equivalence: The KSEA Bipolar Electrotome is substantially equivalent to the predicate devices since the basic features, dimensions, stainless steel, insulation materials and intended uses are similar. The minor differences between the KSEA Bipolar Electrotome and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed:



James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 21 2006

James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
CULVER CITY CA 90230

Re: K061541
Trade/Device Name: KSEA Bipolar Electrotome
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FAS
Dated: August 3, 2006
Received: August 4, 2006

Dear Dr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.



Protecting and Promoting Public Health

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K061541

Device Name: KSEA Bipolar Electrotome

Indications for Use: The KSEA Bipolar Electrotome is intended for use in combination with a resectoscope and a sheath by qualified surgeons to resect, ablate or coagulate tissue via a high frequency electrical current waveform during various endoscopic urological procedures. These procedures include bladder tumor diagnosis and resection, transurethral prostatic and bladder biopsy, transurethral prostatic resection, removal of urethral calculus, and treatment of vesical neck constriction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K061541